## OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

#### **BETWEEN**

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591-6717

AND

# THE UNITED STATES OF AMERICA DEPARTMENT OF HEALTH AND HUMAN SERVICES ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

200 C Street, S.W. WASHINGTON, DC 20515

### CONCERNING

Novel Antibodies against Influenza Virus, Emerging, re-Emerging, and pre-Emerging pathogens

Modification No. 0007

Date: April 29, 2020

PR No.: OS 206444 \$18,693,213; OS 233799 \$19,274,081; OS234612 \$278,812; OS 253326 \$5,751,859; OS 256115 \$92,984,806; OS258142 \$9,247,916

Total Amount of the Agreement: \$182,788,359 (Changed)

Total Estimated Government Funding of the Agreement: \$146,230,687(Changed) Total Estimated Recipient Funding of the Agreement: \$36,557,672 (Changed)

Funds Obligated: \$146,230,687 (Changed)

Period of Performance: September 25, 2017 through May 31, 2026 (Unchanged)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027 (b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 199TWLN (b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994047 (b) (4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994044 (b) (4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027 (b) (4) (CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 199TWLN (b) (4) (CLIN 0003)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 199TWRY

(b) (4) CLIN 0001 and (b) (4) CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 1992019 (b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class: 25106; Appropriation Yr: 2020, CAN: 1992020 (b) (4) CLIN 0001 and (b) (4) CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25103; Appropriation Yr: 2020, CAN: 199COV2

(b) (4) CLIN 0003; (b) (4) CLIN 0004 and (b) (4) CLIN 0005 and

(b) (4) CLIN 0006)

Line of Accounting and Appropriation: Object Class: 25103; Appropriation Yr: 2020, CAN: 199COV2 (b) (4) (CLIN 0004)

<u>PURPOSE</u>: The purpose of this modification is to (1) increase funds to CLIN 0004 due to GMP clinical manufacturing at 2,000L and 10,000L scale.

Beginning with the effective date of this modification, the Government and Other Transaction Agreement holder mutually agree as follows:

## 1. Agreement No.:

HHSO100201700020C Line Items and corresponding values:

Funding for this OTA is revised as follows:

Line Item	Recipient Cost-Share	Government Cost-Share	Total Estimated Cost	Total Government Funds Obligated to Date
0001 - Base	(b) (4)			\$12,118,721
Period				
0001-MERS	(b) (4)			\$164,378
0001-FILO	(b) (4)			\$278,812
0002 - Option 1	(b) (4)			\$22,947,315
0003 - Option 2	(b) (4)			\$16,977,483
0004 - Option 3	(b) (4)			\$68,597,103
0005 - Option 4	(b) (4)			\$ 8,778,490
0006 - Option 5	(b) (4)			\$14,233,381
0006 - Option 5	(b) (4)		*	\$2,135,007
*-Contingency fee	(b) (4)		Total:	\$146,230,690

Note:

- (i) Internal Expenses. Internal expenses will be determined based on actual labor hours for the activities performed, multiplied by a single, fully-burdened FTE rate not subject to true-up, calculated for the Research & Development organization which will be working on the programs under this Agreement. This rate will be adjusted annually based on the CPI adjustment methodology outlined in the final cost proposal. The Contracting Officer will request documents supporting adjustments in the CPI.
- (ii) External (Subrecipient or Affiliates) Expenses. External expenses will be billed based on actual third-party charges submitted to Regeneron.
- (iii) Drug Supply. Drug supply manufactured at a Regeneron facility will be billed based on a fully-allocated cost methodology which includes direct variable, direct fixed and indirect cost allocations (See the 9/14/17 proposal). Drug manufactured by a third party contract manufacturer will be billed based on actual third party charges submitted to Regeneron.
- (iv) G&A. G&A expenses will be billed for external expenses and drug supply based on a set rate not subject to true-up. A negotiated rate agreement or rate documentation shall be provided in the subrecipient agreement.

All other terms and conditions remain the same.

FOR THE UNITED STATES OF AMERICA OFFICE OF ACQUISITION MANAGEMENT, CONTRACTS & GRANTS SECRETARY FOR PREPAREDNESS AND RESPONSE

Carl A. Newman - S Digitally signed by Carl A. Newman - S Date: 2020.04.29 11:24:01 -04'00'

(Signature) (Date) Carl A. Newman Other Transaction Agreement Officer, BARDA

FOR Regeneron Pharmaceuticals, Inc.

(b) (6) 4/28/2020 (Date)

Robert E. Landry,

Executive Vice President, Finance and Chief Financial Officer, Regeneron Pharmaceuticals, Inc.

END OF MODIFICATION No. 0007 TO HHSO100201700020C